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IPAB: The Controversial Consequences for Medicare and Seniors

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Scott Gottlieb, M.D. Resident Fellow American Enterprise Institute Mr. Chairman, Mr. Ranking Member, thank you for the opportunity to testify today before the Committee. I have a longer working paper that contains some supporting details to my oral testimony today that I would like to submit for the record.

The Independent Payment Advisory Board (IPAB) was created based on the premise that decisions about the pricing of health benefits offered by Medicare are simply too contentious to be adequately handled by our present political system.

But these decisions are precisely the kinds of consequential choices that should be subject to close public scrutiny and an open, rigorous, and transparent decision-making process that engages with Medicare's stakeholders.

Changes to the way Medicare pays for and covers medical services affect too many people in significant ways to be made behind the closed doors of an insulated committee. How Medicare prices medical products and services has sweeping implications across the entire private marketplace. These decisions are some of the most important policy choices that we make inside our healthcare system.

Problems with IPAB's Construction

IPAB is not the right body to discharge these kinds of matters. There are some considerable shortcomings with the way that IPAB is structured, and the manner in which the board is tasked with operating under current law.

IPAB was purposely construed in legislation to take decisions about how to cut Medicare's spending on medical products and services out of any public debate and, instead, vest them in the hands of a sequestered board of appointed individuals.

The board has no obligation to engage in public notice and comment that is customary to regulatory agencies whose decisions have similarly broad implications for patients, healthcare providers, and medical product developers.

IPAB's decisions are restricted from judicial review.

In creating IPAB, Congress provided affected patients, providers, or product developers with no mechanism for appealing the board's pronouncements.

IPAB's recommendations will be fast tracked through Congress, in a way that provides for only a veneer of Congressional review and consent. This was probably a nod to Constitutional issues related to the separation of powers between the Executive and legislative branches rather than a desire for genuine Congressional input. For practical purposes, the IPAB has been given the authority to legislate.

The cumulative effect of the rules for appointing members to IPAB will almost guarantee that most of its outside members hail from the insular ranks of academia.

In short, every aspect of this board was cleverly designed to remove significant decisions about Medicare cuts from public debate and scrutiny.

But most significantly, IPAB is unlikely to take steps that actually improve the quality of medical care and the delivery of services under Medicare.

That's because IPAB does not have any practical alternative to simply squeezing prices in the Medicare program. Owing to the way it is set up, IPAB is statutorily required to achieve its savings in the short term. The problem we have in Medicare is not a short-term problem that can be fixed with price squeezes. We have already been trying and failing at that for the last 45 years. It is a problem with the existing price controls that erode healthcare productivity and Medicare's outdated fee-for-service payment system that leads to inefficient medical care and inadequate support for better, more innovative ways of delivering healthcare services.

IPAB is an unsuitable solution tilting at the wrong problem. If the architects of government-run health programs bemoan that fact that it is hard to achieve unpopular cuts to the program because the political process often stymies these efforts, I would submit that this is an argument against running these health programs out of Washington. It is not an indictment of the open, transparent, and vigorous process that traditionally governs serious policymaking.

IPAB's Likely Pursuits

The first question is: "What is IPAB likely to do?" Will its decisions have perverse impacts on some of Medicare's constituents precisely because IPAB's decisions sidestep the checks that normally protect against regulatory over-reaching?

Because of IPAB's mandate to come up with potentially big savings, and its composition of largely generalist academics, IPAB will not have the opportunity or capacity to adjudicate individual medical treatments and services. IPAB will operate at a higher level, confining its work to one of three broader areas of policymaking:

First, it will lower the price Medicare pays for services closer to Medicaid rates.ⁱⁱ

Second, it will extend government price schedules that currently exist in one aspect of the market to new places inside the Medicare program. Since hospitals and other service providers have gotten themselves politically excluded from IPAB's initial reach, the board's payment cuts will fall disproportionally on the reimbursement of, and in turn access to, medical technology such as drugs and medical devices.

If you want a better indication of what these proposals might comprise, I would look to the recommendations made by MedPAC that CMS failed to implement (often because of political resistance) as a guide to the ideas IPAB is likely to pursue.ⁱⁱⁱ

Third, and finally, IPAB will confer CMS with new authorities that will enable the Medicare agency to make more granular decisions about what medical products and services it chooses to cover. Rather than making the tough clinical judgments themselves, the IPAB would grant CMS authority to rely on judgment of the agency's largely thin clinical staff about the relative benefits of competing treatments.

It is this last area of policymaking that could have the most significant implications. While the new law bars IPAB from reducing the coverage of specific benefits, there is nothing barring IPAB from giving CMS authorities to engage in similar activities.

So IPAB could well confer CMS with constructs such as Least Costly Alternative (LCA) authority, or the authority to consolidate drugs, devices, equipment, or services, under the same payment code. The combined effect of these new powers would effectively give CMS the ability to engage in tacit forms of reference pricing for a wide range of medical products and services.

In effect, CMS would be able to say, among a variety of therapeutic options, we think the different approaches are clinically interchangeable. We – CMS -- will only reimburse at a rate that pays for the cheapest alternative. Low reimbursement rates for higher-priced technology or services would effectively bar their use. CMS has long wanted these powers. The agency went to federal court three times – in both Republican and Democratic administrations – seeking LCA authority, for example. iv

These authorities have the effect of making CMS a clinical arbiter, deciding what treatments are sufficiently similar that they can be used interchangeably for one another. The problem is that CMS has no tradition of making these kinds of decisions. As a consequence, it has little capacity to make the required judgments. I believe many in Congress realize this, and I know many stakeholders recognize it.

This isn't just a question of expertise. It is also a question of whether these kinds of personal medical choices should be made in the first place by a remote agency that is far removed from circumstances that influence clinical decision-making.

Moreover, under IPAB's current charter, it only gets to make recommendations when the rate of Medicare growth is expected to exceed CPI by a certain measure. This means IPAB may only have the chance to legislate once every several years.

As a result, the institutional instinct of the board will be to over-reach as opposed to moderate its positions – to achieve a higher degree of savings. Some members will worry they may not get another chance to push favored ideas so they will try and get their recommendations implemented when they have the opportunity. Similarly, members may decide that it is politically easier to issue proposals once every several years rather than have to come up with a new set of policies every year.

The Consequences of IPAB's Actions

So at a broad level, this is how I see IPAB flexing its powers. The final question is: What are the consequences of these policies that IPAB is likely to pursue?

The requirement for public scrutiny of regulatory decisions affords a measure of thoughtfulness, rigor, and moderation that I believe are essential to making decisions as important as how we cover health benefits in this nation.

Moreover, because Medicare affects so many people, and drives so much of the coverage decisions made in the private market, its actions have wide impact.

In short, Medicare is no ordinary payer. Its decisions should be more transparent, more expertly guided, and more subject to debate and public scrutiny and opportunities for appeal precisely because of the wide-ranging impact.

Yet the constitution of IPAB, and the staffing of CMS, renders this entire scheme far less transparent and rigorous and open than the average private health plan.

This will have implications for patients and providers. It will also have significant implications for those developing new medical technologies. It will make that process more uncertain, more costly, and less attractive to new investment.

Similar processes in Europe show that these kinds of schemes make it far less likely that entrepreneurs can develop new therapies that effectively re-price the initial treatment of significant diseases, no matter how much benefit those treatments may potentially deliver. Prices inside different therapeutic areas become arbitrarily capped, reducing incentives to significant new investment.

Already, it can take years for effective new therapies to win reimbursement in Europe; long after they are paid for by private health plans here in the U.S. Market access to new treatments in Europe lag the U.S. as a consequence. The new authorities IPAB will confer on CMS will bring our process far closer to Europe. V VI

Combined with increasing regulatory requirements at FDA that have made early discovery and development far more costly (front-loading many of the costs of drug development) IPAB's additional costs and uncertainties could leave more investors with the view that biomedicine is not a viable opportunity for early stage investment. Here is the U.S., we are already seeing less new company formation in the biotech sector, as business models adjust to the challenges of the regulatory and reimbursement climate. Look no further than San Diego, which was once a bustling hub of biotech entrepreneurship. Today it looks more like a biotech ghost town.

Conclusion

Can you imagine a private health plan making retrospective decisions about coverage and payment after it had contracted with providers and beneficiaries, and

then proclaiming itself exempt from any appeals by patients, judicial review by beneficiaries or providers, and relieved of any serious political scrutiny?

This is effectively how IPAB will operate, not by its own fidelity but by legislative design, according to its Congressional mandate. Congress has created the very constructs that it derides, and penalizes, when private companies undertake them.

Medicare must continue to implement reforms to align its coverage and payment policies with the value delivered to beneficiaries. The only consistent way is to develop policies that enable these decisions to be made in a de-centralized fashion, based on the actual demand of consumers and providers. It's not to consolidate these judgments into an increasingly narrow band of government actors.

Congress needs to focus on real ways to get longer-term savings, like premium support, modernizing benefits in traditional Medicare, and paying for better outcomes. IPAB makes it even harder to do all these things.

If Congress believes that the political process is incapable of making enduring decisions about the payment of medical benefits, then all of this is an argument for getting the government out of making these kinds of judgments in the first place.

It is not an argument for creating some kind of paramount and insular panel that is cloistered from the usual scrutiny, to take decisions that other Federal entities have failed to adequately discharge -- precisely because those decisions couldn't survive public examination, scientific questioning, and close political inspection.

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ⁱ "The terms of the Act attempt to "entrench" the procedures themselves against change by requiring a super majority to amend them, as well as to discontinue the automatic IPAB-implementation process. The Act also purports to restrict the ability of future Congresses to enact certain policy changes related to Medicare in other legislation, not just the IPAB-implementing measure. How these entrenching provisions will be reconciled with the well- established constitutional right of each chamber of Congress to make the rules of its own proceeding, and how or if one Congress can broadly regulate the actions of a future Congress in this way, will likely only be clarified in practice." From the Congressional Research Service, CRS Report for Congress, The Independent Payment Advisory Board David Newman and Christopher M. Davis, November 30, 2010 "https://www.cms.gov/ReportsTrustFunds/Downloads/2011TRAlternativeScenario.pdf. See figures 1 and 2. By the end of the projection period, Medicare and Medicaid payment rates for inpatient hospital services would both represent roughly 33% of the average level for private health insurance. Under current law, Medicare rates for physician services would eventually fall to 27% of private health insurance levels by 2085 and to less than half of the projected Medicaid rates. The continuing slower growth would occur as a result of negative update adjustment factors caused by growth in the volume and intensity of physician services that exceeds the increase specified by the SGR formula. iii See attached document outlining MedPAC's never implemented recommendations

 $^{^{\}mathrm{iv}}$ Gottlieb, Scott. How the U.S. Government Rations Health Care. The Wall Street Journal, October 1, 2009. P A24

^v Mitchell, Peter. Price controls seen as key to Europe's drug innovation lag. Nature Reviews Drug Discovery. 6, 257-258 (2007).

vi Cristian Vladescu, Simona Baculea, Nona Chirac. The Burden of Cancer and Market Access for New Oncology Drugs in European Countries. Management in Health, Vol 13, No 2 (2009) Available at http://journal.managementinhealth.com/index.php/rms/article/view/23/76